UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,985	10/23/2006	Andreas M. Zeiher	05552.1459	1864

22852 7590 03/29/2011

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
03/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,985	ZEIHER ET AL.	
	Examiner	Art Unit	
	LISA COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-21 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/11 has been entered.

2. Claims 1-19 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Currently claims 20, 21, and 23-32 are under consideration.

4. Rejections and/or objections of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTIONS NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayes-Genis et al. (The New England Journal of Medicine, Vol.345, No.14, October 4, 2001, pages 1022-1029).

Bayes-Genis et al. disclose methods of measuring PAPP-A in acute coronary syndromes. See page 1026 and figure 2. PAPP-A was found to be a marker for acute coronary syndrome. See entire reference.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

II. Claims 20, 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) in view of Corsini et al. (Pharmacology & Therapeutics, Vol.84, 1999, pages 413-428).

Schonbeck et al. disclose methods of measuring soluble CD40L in patients with unstable angina. The immune-signaling dyad CD40/CD40L promotes atherogenesis and is elevated with unstable angina.

Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) differ from the instant invention in not specifically teaching the administration of statins as a therapeutic vascular agent to a patient.

However, Corsini et al. teach procedures for administering statins to inhibit 3-hydroxy-3methyl-glutaryl coenzyme A. See abstract and Table 2. Statins can ameliorate vascular atherosclerosis and reduce cardiovascular-related morbidity and mortality in patients with or without coronary artery disease (CAD) symptoms. See page 414 - 1st column, Introduction. It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to treat the detected vascular patients of Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) with the statin drugs of Corsini et al. because Corsini et al. taught that Statins can ameliorate vascular atherosclerosis and reduce cardiovascular-related morbidity and mortality in patients with or without coronary artery disease (CAD) symptoms. See page 414 - 1st column, Introduction.

Response to Arguments

Applicant contends that the cited art does not teach the monitoring of therapy with regard to the adjustment of treatment in order to improve the pathophysiological condition of an individual. This argument was carefully considered but not found persuasive because these limitations are not recited in the claims. The instant claims merely require the administration of statins and the detection of sCD40L. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., monitoring the improvement of the pathophysiological condition of an individual) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

III. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being obvious over Maglione et al. (IL Farmaco, Vol.55, pages 165-167, 2000) in view of Roger et al. (Journal of the American College of Cardiology, 1999, Vol.34, No.1, pages 155-162).

Maglione et al. disclose the measurement of PIGF-1 and VEGF in the measurement of various disorders including ischemic myocardium and infarct size. See abstract and page 267.

Maglione et al. differ from the instant invention in not specifically teaching the detection of BNP (B-type natruiuretic peptide) or brain natriuretic peptide.

However, Roger et al. disclose methods measuring BNP and its effects on hemodynamics. BNP is elevated in patients with heart failure, and serves as a sensitive and specific serologic marker for left ventricle dysfunction. BNP is disclosed as a component in the modulation of cardiac and vascular function and fluid status. See page 155. The studies included stroke patients (cerebral injury). See Table 1 on page 156. The measurement and monitoring of BNP was found useful in the assessment of the drug nesiritide. See 161.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to evaluate BNP as taught by Roger et al. in the method Maglione et al. because Roger et al. taught that BNP is a component in the modulation of cardiac, vascular function, and fluid status. Further including stroke. See pages 155-156. One of ordinary skill in the art would have evaluated BNP in order to monitor blood flow as it relates to brain/cerebral disorders.

The use of two known cerebral markers in combination to evaluate cerebral injury is obvious because expected beneficial results are evidence of obviousness. In re Skoll (CCPA 1975) 523 1392, 187 USPQ 481; Ex parte Luck (BPAI 1993) 28 PQ2d 1875. In this instance the use of multiple markers would provide multiple data for precise and accurate measurement of the cerebral injury.

A long line of cases have held that the mere use of different starting materials, whether novel or known, in a conventional process to produce the result one would expect therefrom does not render the process unobvious. For example see, In re Surrey et al. (CCPA 1963) 319 F.2d 233, 138 USPQ 67; In re Kanter (CCPA 1968) 399 F2d 249, 158 USPQ 331.

IV. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being obvious over Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) in view of Roger et al. (Journal of the American College of Cardiology, 1999, Vol.34, No.1, pages 155-162).

Please see Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) as set forth above.

Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) differ from the instant invention in not specifically teaching the detection of BNP (B-type natruiuretic peptide) or brain natriuretic peptide.

However, Roger et al. disclose methods measuring BNP and its effects on hemodynamics. BNP is elevated in patients with heart failure, and serves as a sensitive and specific serologic marker for left ventricle dysfunction. BNP is disclosed as a component in the modulation of cardiac and vascular function and fluid status. See page 155.

The studies included stroke patients (cerebral injury). See Table 1 on page 156. The measurement and monitoring of BNP was found useful in the assessment of the drug nesiritide. See 161.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to evaluate BNP as taught by Roger et al. in the method Schonbeck et al. (Circulation, 2001, Vol.104, pages 2266-2268) because Roger et al. taught that BNP is a component in the modulation of cardiac, vascular function, and fluid status. Further including stroke. See pages 155-156. One of ordinary skill in the art would have evaluated BNP in order to monitor blood flow as it relates to brain/cerebral disorders.

The use of two known cerebral markers in combination to evaluate cerebral injury is obvious because expected beneficial results are evidence of obviousness. In re Skoll (CCPA 1975) 523 1392, 187 USPQ 481; Ex parte Luck (BPAI 1993) 28 PQ2d 1875. In this instance the use of multiple markers would provide multiple data for precise and accurate measurement of the cerebral injury.

A long line of cases have held that the mere use of different starting materials, whether novel or known, in a conventional process to produce the result one would expect therefrom does not render the process unobvious. For example see, In re Surrey et al. (CCPA 1963) 319 F.2d 233, 138 USPQ 67; In re Kanter (CCPA 1968) 399 F2d 249, 158 USPQ 331.

7. For reasons aforementioned and already of record, no claims are allowed.

Response to Arguments

Applicant's amendment and response have been carefully considered and found persuasive. Accordingly, new grounds of rejections are presented herein.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Patent Examiner
Art Unit:1641
Remsen
571-272-0816
3/27/11

/Lisa V. Cook/
Primary Examiner, Art Unit 1641